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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,339	03/12/2004	James W. Voegelé	END5241USNP	9931

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EXAMINER

NGUYEN, HUONG Q

ART UNIT	PAPER NUMBER
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3736

MAIL DATE	DELIVERY MODE
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10/30/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/800,339	Applicant(s) VOEGELE, JAMES W.	
	Examiner HELEN NGUYEN	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,7 and 21-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5, 7, and 21-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/6/2009 has been entered.
2. Claims 1, 21, 25-26, and 34 are amended. **Claims 1, 5, 7, and 21-34** remain pending and under prosecution.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. **Claim 34** is rejected under 35 U.S.C. 102(b) as being anticipated by Truckai et al (US Pat No. 6485436).

5. Truckai et al disclose a biopsy for obtaining a tissue sample at a sample site within a patient, the biopsy device comprising:

a hollow tissue piercing member 10A having a tissue piercing distal end 16 comprising an energizable electrode (entire outer sleeve is electrode Col.6: 63-64) and a tissue receiving port

Art Unit: 3736

32 spaced proximally from the tissue piercing distal end, the hollow tissue piercing member insertable in a tissue mass within a patient, best seen in Figure 1 and 7;

a hollow cutter 10B translatable within the hollow tissue piercing member for severing tissue received in the tissue receiving port at a sample site within the tissue mass, best seen in Figure 2-3;

at least one electrode 195 disposed outwardly of the hollow tissue piercing member, wherein at least a portion of the electrode is positioned proximally of the a distal most portion of the tissue receiving opening and wherein at least a portion of the electrode is positioned distally of a proximal most portion of the tissue receiving opening, best seen in Figure 7.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. **Claims 1 and 5** are rejected under 35 U.S.C. 103(a) as being unpatentable over Burbank et al (US Pat No. 6471700) in view of Wardle et al (US Pub No. 20020120211), further in view of Truckai et al (US Pat No. 6485436).

8. In regards to **Claim 1**, Burbank et al discloses a biopsy device comprising:

a tissue piercing element 24, 190 having a conductive tip electrode 28, 192, best seen in Figure 1 and 12 respectively;

Art Unit: 3736

a hollow sleeve 12 adapted to receive the tissue piercing element therein, best seen in Figure 3 and 13, the sleeve comprising an open proximal end, a distal end 18, a sidewall extending between the proximal end and the distal end, and a tissue receiving opening 16 disposed intermediate the proximal end and the distal end, wherein the tissue receiving opening is formed laterally in the sidewall, best seen in Figure 1, and the sleeve comprising a connector 20 for releasably attaching the sleeve to a biopsy device 24, 190 comprising the tissue piercing element, best seen in Figure 3 and 13 (Col.6: 10-34);

wherein the tip electrode is disposed distal of the distal end of the hollow sleeve when the tissue piercing element is received in the hollow sleeve, best seen in Figure 3 and 13.

9. However, Burbank et al do not disclose at least two electrodes disposed on the sleeve. It is however noted that Burbank et al teach the use of electrocautery unit 150 in conjunction with hollow sleeve 12 to effectively provide coagulation, i.e. cauterize the region where samples are taken to stop bleeding and reduce the probability of infection, best seen in Figure 15 (Col.12: 30-39).

10. Wardle et al teach an analogous hollow sleeve 14 with at least two electrodes 20 disposed on the sleeve, the at least two electrodes capable of and thus adapted to provide coagulation, best seen in Figure 2B (left and right) (¶0030). Truckai et al disclose an analogous device comprising an electrode 196 disposed on an outer sleeve 110A such that at least a portion of the electrode is positioned proximally of the a distal most portion of a tissue receiving opening and wherein at least a portion of the electrode is positioned distally of a proximal most portion of the tissue receiving opening, best seen in Figure 7, to effectively cauterize the biopsy area (Col.6: 50-63).

Art Unit: 3736

11. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the hollow sleeve of Burbank et al to have at least two electrodes disposed in the manner described above on the sleeve and are adapted for providing coagulation as taught by Wardle et al and Truckai et al respectively, to predictably provide a more integral device wherein the hollow sleeve advantageously provides electrodes for cauterization of the biopsy site after a sample is taken.

12. In regards to **Claim 5**, Wardle et al and Truckai et al disclose first and second electrodes associated with the edges of the tissue receiving opening, best seen in Figure 1 of Wardle et al and Figure 7 of Truckai et al.

13. **Claims 21-25, and 27-33** are rejected under 35 U.S.C. 103(a) as being unpatentable over Wardle et al in view of Shadduck (US Pat No. 6740082).

14. In regards to **Claim 21**, Wardle et al disclose a biopsy device comprising:

a hollow sleeve (14) comprising a proximal end, a distal end, a unitary sidewall extending from the distal end to the proximal end, best seen in Figure 2B, and a lateral opening (22, 26) formed through a portion the unitary sidewall, wherein the lateral opening is configured to receive tissue, wherein the sleeve is configured to axially receive a portion of a biopsy probe instrument (44), and the sleeve comprising a connector for releasably attaching the sleeve to the biopsy probe instrument best seen in Figure 4, wherein the connector is defined as the end portion of the sleeve by thumbwheel 32 at which point said biopsy probe instrument is insertedly

Art Unit: 3736

attached to the sleeve, also shown in Figure 1;

at least one electrode (20) disposed on an outer surface of the sleeve, best seen in Figure 2B;

a conductive tip electrode (72) slidably received within the hollow sleeve (¶0040), best seen in Figure 1.

15. However, Wardle et al do not disclose said at least one electrode disposed proximally of a distal most portion of the lateral opening. Shadduck discloses an analogous sleeve comprising electrodes (45a-b) disposed proximally of a distal most portion of a lateral opening (76), as an effective configuration for the desired tissue contact, best seen in Figure 6B. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the positioning of the electrode of Wardle et al such that said electrode is disposed proximally of a distal most portion of the lateral opening, as taught by Shadduck, to produce an effective electrode configuration that enhances tissue contact to achieve the predictable result of proper tissue biopsy.

16. In regards to **Claim 22**, Wardle et al disclose the lateral opening (22) is located proximal of the distal end of the sleeve, wherein a portion of the sleeve separates the lateral opening from the distal end of the sleeve, best seen in Figure 2B.

17. In regards to **Claim 23**, Wardle et al disclose a portion of the sidewall extends unitarily from the proximal end of the sleeve to the distal end of the sleeve, best seen in Figure 2B.

18. In regards to **Claim 24**, Wardle et al disclose a connector operable to selectively couple

Art Unit: 3736

the sleeve with the biopsy probe instrument, best seen in Figure 4.

19. In regards to **Claim 25**, Wardle et al disclose the sleeve (14) has an open distal end (22, 26), which is an opening at the distal end, wherein the sleeve is configured to axially receive a biopsy probe (44) having a distal tip (72) for penetrating tissue, and wherein the sleeve is configured such that the distal tip of a biopsy probe extends distally from the open distal end of the sleeve when the sleeve is disposed axially over the biopsy probe, best seen in Figures 2-3.

20. In regards to **Claim 27**, Wardle et al disclose the biopsy probe instrument is configured to communicate electrical signals to the electrodes (20) when the sleeve (14) is coupled with the biopsy probe instrument (¶0034-0035).

21. In regards to **Claim 28**, Wardle et al disclose the electrodes (20) are configured and capable to receive communication of electrical signals for a power source independent of the biopsy probe instrument.

22. In regards to **Claim 29**, Wardle et al in combination with Shadduck disclose first and second electrodes positioned along opposites of the lateral opening (22, 26), wherein such variable positioning is obvious to one of ordinary skill in the art, such as that shown in Shadduck Figure 6A.

23. In regards to **Claim 30**, Wardle et al in combination with Shadduck disclose the one or more electrodes comprises an annular electrode positioned at the distal end of the sleeve (14).

24. In regards to **Claim 31**, Wardle et al in combination with Shadduck disclose the one or more electrodes comprises a pair of electrodes separated by an electrode gap, best seen in Figure 6B (Shadduck).

Art Unit: 3736

25. In regards to **Claim 32**, Wardle et al disclose the distal end of the sleeve (14) is open (22, 26), wherein there is an opening at the distal end of the sleeve, best seen in Figure 2B.

26. In regards to **Claim 33**, Wardle et al in combination with Shadduck disclose two electrodes, each electrode extending lengthwise in a direction parallel to the longitudinal axis of the sleeve, and at least a portion of each electrode disposed proximally of a distal most portion of the lateral opening, best seen in Figure 6B (Shadduck).

27. **Claim 7** is rejected under 35 U.S.C. 103(a) as being unpatentable over Burbank et al ('700), Wardle et al, and Truckai et al in view of Burbank et al (US Pat No. 6540695) and Russell et al (US Pat No. 6500144).

28. Burbank et al ('700) in combination with Wardle et al and Truckai et al as modified in the manner above disclose at least two electrodes disposed on an outer surface of the sleeve but are silent as to the dimensions of the electrodes (20). Burbank et al teach electrodes (18), best seen in Figure 1, with a width dimension of between about 3 mm and about 8 mm (Col.11: 58-67). Russell et al teach electrodes (20), best seen in Figure 1, with a length dimension of between about 20 mm and about 40 mm (Col.7: 4-15) as effective sizes for the desired tissue application within the body. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the at least two electrodes of Burbank et al ('700) as modified by Wardle et al and Truckai et al with a width of about 3mm – 8 mm and a length of about 20 mm – 40 mm, as taught by Burbank et al ('695) and Russell et al respectively, to dimension the electrodes at an appropriate size for the desired tissue application.

Art Unit: 3736

29. **Claim 26** is rejected under 35 U.S.C. 103(a) as being unpatentable over Wardle et al in view of Shadduck, further in view of Burbank et al (US Pat No. 5526822).

30. Wardle et al in combination with Shadduck disclose the sleeve (14) with a lateral opening (22, 26) for tissue communication and a biopsy probe instrument (44) but do not disclose said biopsy probe instrument with a tissue receiving window. Burbank et al disclose an analogous biopsy probe instrument (468) with a tissue receiving window (476) disposed within an analogous sleeve (444) also with a lateral opening (446), best seen in Figure 14A, wherein when the sleeve is coupled with the biopsy probe instrument, the sleeve is configured such that the lateral opening permits communication of tissue through the lateral opening of the sleeve and through the tissue receiving window of the biopsy probe instrument (Col.18: 53-56). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the biopsy probe instrument of Wardle et al as modified by Shadduck to include a tissue receiving window, as taught by Burbank et al, such that when said biopsy probe instrument is coupled to the sleeve the lateral opening of the sleeve enables communication of tissue through the lateral opening and through the tissue receiving port to ensure the prolapse and subsequent effective capture of the tissue.

Response to Arguments

31. Applicant's arguments with respect to **Claims 1, 5, 7, and 34** have been considered but are moot in view of the new ground(s) of rejection.

32. Applicant's arguments with respect to **Claims 21-33** have been fully considered but they are not persuasive. Applicant contends that Wardle et al in combination with Shadduck do not

Art Unit: 3736

teach a sleeve having at least one electrode and a conductive tip electrode slidably received within the hollow sleeve. However, it is noted that Wardle et al teach hollow sleeve 14 with at least one electrode as elaborated above and a conductive tip electrode 72 slidably received within the hollow sleeve as attached to biopsy probe instrument 44, best seen in Figure 1 (¶0040).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HELEN NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on Monday - Friday, 9 am - 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. N./

Application/Control Number: 10/800,339

Page 11

Art Unit: 3736

Examiner, Art Unit 3736

/Max Hindenburg/

Supervisory Patent Examiner, Art Unit 3736